

## REMARKS

### **I. Status of Claims**

Claims 73-86 are pending in the application. Claims 73, 75, 79 and 83 have been amended to recite that the soy bean extract (b) is a nondenatured soybean extract of the entire soybean which contains nondenatured soybean trypsin inhibitor. Support for these amendments can be found in the Specification, at least at paragraphs [0010] and [0011]. Accordingly, no new matter has been introduced by this Amendment.

### **II. Priority Determination**

Applicants gratefully acknowledge the Examiner's reconsideration of the priority determination. As the Examiner has not repeated his objection, Applicants assume that the Examiner agrees that priority should extend to parent patent application Serial No. 09/110,409.

### **III. Claim Rejections Under 35 USC 103(a)**

The Examiner has rejected claims 73-86 under 35 U.S.C. 103(a) as allegedly being unpatentable over CN166960A ("Jin") in view of U.S. Patent No. 5,034,228 ("Meybeck et al.") and further in view of U.S. Patent No. 5,338,547 ("Kennedy"). Applicants respectfully request reconsideration of the foregoing rejection in view of the ensuing remarks.

The presently claimed invention relates to a method of treating acne comprising topically administering to a mammal in need of treatment therefor an effective amount of a composition comprising (a) tretinoin or retinol and (b) a nondenatured soybean extract of the entire soybean which contains nondenatured soybean trypsin inhibitor.

As discussed in the Specification, Applicants have surprisingly discovered that compositions containing nondenatured soy extracts and contain non-denatured soybean trypsin inhibitor are capable of reducing retinoid-induced irritation or redness without affecting retinoid activity. See Specification, page 6, lines 23-25 and page 11, lines 16-20. Indeed, Examples 8-14 of the present Specification demonstrate the unexpected superior properties of the claimed invention. As demonstrated by the Examples, the addition of the soy products used in the presently claimed method reduced the redness associated with

retinoid treatment, without any negative effect on the retinoid activity and possibly even enhances the quality of the treated skin. The references relied upon by the Examiner fail to render obvious the method of treating acne recited by the present claims and in no way teach or suggest the unexpected superior properties of the claimed method.

Jin relates to a "complex spirulina beauty masque powder" which contains the following materials: 20 to 40 grams of spirulina; 8 to 30 grams of pearl powder; 20 to 40 grams of pure pollen; 10 to 30 grams of mung bean flour; 5 to 12 grams of soy protein isolate powder; 8 to 12 grams of powdered silkworm larvae; 6 to 15 grams of blitilla tuber powder and 6 to 15 grams of talcum powder.

The Examiner recognizes that Jin fails to teach the inclusion of tretinoin and relies upon Meybeck et al. as teaching that tretinoin can be used to treat acne. However, the Examiner has failed to provide any teaching in either of Jin or Meybeck et al. that would provide one of ordinary skill in the art with the motivation to incorporate tretinoin into the Jin beauty masque. Meybeck et al. specifically teaches that tretinoin and the structural analogues thereof are irritating to the skin. In fact, as discussed in the present Specification, the undesirable effects of retinoids are well known in the art. See Specification, page 3, lines 2-13. In an effort to counter the irritating effects of retinoids, Meybeck et al. teaches the incorporation of a retinoid or a structural analogue thereof into specific hydrous lipidic lamellar phases.

Contrary to the Examiner's position, one of ordinary skill in the art would not incorporate tretinoin into the Jin beauty masque since Meybeck et al. specifically teaches that tretinoin is known to be irritating to the skin. Further, there is absolutely no teaching or suggestion that the specific hydrous lipidic lamellar phases taught by Meybeck et al. could successfully be incorporated into the "complex" spirulina beauty masque powder taught by Jin. In fact, one of ordinary skill in the art would have absolutely no expectation that the hydrous lipidic lamellar phases would remain intact in the specific powder taught by Jin. Accordingly, one of ordinary skill in the art would simply not be motivated to incorporate tretinoin into the Jin compositions.

The Examiner also recognizes that Jin and Meybeck et al. fail to teach the inclusion of a nondenatured soybean extract of the entire soybean which contains non-denatured soybean

trypsin inhibitor. Indeed, the Examiner states “Meybeck fails to teach that the treatment method comprises soy powder.” The Examiner relies upon Kennedy as allegedly curing this deficiency. Specifically, the Examiner states “It would have been obvious to one in the method of treatment taught by Jin for the Bowman-Birk Inhibitor Concentrate (a denatured soy product) into a paste or milk forms as taught by Jin to include treating acne taught by Meybeck.” The Examiner’s position here is unclear. It appears that the Examiner is arguing that it would be obvious to include BBIC into the Jin compositions and then to use that composition to treat acne. Applicants respectfully disagree. There is no teaching or suggestion that BBIC would be useful in acne treating compositions. In fact, Kennedy does not even mention the treatment of acne, much less, give any suggestion that a nondenatured soybean extract of the entire soybean which contains non-denatured soybean trypsin inhibitor would be useful in a composition to reduce tretinoin side effects while treating acne as discovered by Applicants.

Further, even if one of ordinary skill in the art were somehow motivated to incorporate BBIC into the Jin compositions, one would not arrive at the claimed invention. Because Kennedy’s BBIC composition is obtained by organic extraction, it is denatured. The process of organic extraction denatures or removes most of the proteins of the bean and concentrates a very stable single protein (BBI). Accordingly, Kennedy in no way relates to “a nondenatured soybean extract of the entire soybean which contains non-denatured soybean trypsin inhibitor.”

The Examiner also states “Since Jin’s method of treatment comprises natural bean flour, one of ordinary skill in the art would have been motivated to substitute the mung bean flour with a soybean flour with a reasonable amount of success.” See Office Action, page 5. However, Kennedy discloses a method of treating pre-malignant tissue and the inhibition of skin cancer by topically applying a composition containing a Bowman-Birk Inhibitor Concentrate (BBIC). There is absolutely no teaching or suggestion that either mung bean flour or soybean flour used as an ingredient in a cosmetic product could or should be replaced with BBIC which is taught to be a cancer preventative agent. Kennedy does not in any way relate to cosmetic composition much less to acne treating compositions. In fact, Kennedy does not teach any use of BBIC other than for the inhibition of cancer. Accordingly, there

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would be no motivation to incorporate BBIC and, for the reasons discussed above there would be no motivation to incorporate tretinoin, into the Jin compositions. Further, as discussed above, even if one of ordinary skill were somehow motivated to do so, one would not arrive at the claimed invention. As discussed above, none of the references relied upon by the Examiner, taken alone or in combination, teach "a nondenatured soybean extract of the entire soybean which contains non-denatured soybean trypsin inhibitor," much less, the use thereof in combination with retinoid or tretinoin in a method to treat acne.

For all these reasons, Applicants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness and the rejection should be withdrawn.

### **III. Conclusion**

For the reasons set forth above, Applicants respectfully request withdrawal of all outstanding objections and rejections and that a timely Notice of Allowance is issued in this case.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750JPB0430CIP/JPB. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 10-0750JPB0430CIP/JPB.

Respectfully submitted,

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